

Taking Double Cut, Surgeons Implant Their Own Devices

By
JOHN CARREYROU And

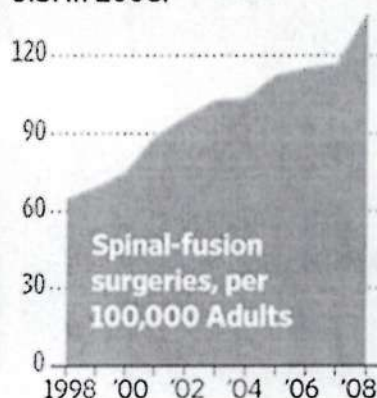
TOM MCGINTY
October 8, 2011

JACKSON, Miss.—On April 7, a 48-year-old Baptist preacher named Gary Steve Moore had spinal-fusion surgery at St. Dominic Hospital here. Hours later, he was dead.

Mr. Moore had been suffering from a degenerating disk in his lower back. Two spine surgeons who later reviewed his medical records say his history of heart disease and bowel obstructions made him a poor candidate for a 360-degree spinal fusion, a complex operation that involved opening up both his abdomen and his back.

Growth Sector

Spinal fusion was the 16th most common hospital inpatient procedure in the U.S. in 2008.



Source: 'Spinal Fusion in the United States: Analysis of Trends from 1998 to 2008' by Sean Rajaei, Hyun Bae, Linda Kanim and Rick Delamarter

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His neurosurgeon, Adam Lewis, felt that "surgery was indicated" given Mr. Moore's worsening back pain and the fact that more conservative treatments he had tried, such as physical therapy, had provided no relief, says Dr. Lewis's lawyer, Whit Johnson.

EXHIBIT 1

However, there was one element of the surgery that Dr. Lewis didn't mention to the patient, according to his widow: The surgeon was part-owner of the company, Spinal USA, that makes the devices he implanted in Mr. Moore's spine.

Dr. Lewis's part-ownership of a medical-device company is far from unique in the world of back surgery. Rather than use spinal implants from third-party manufacturers, scores of surgeons have started their own device makers to churn out similar designs, putting themselves in a position to benefit financially from the hardware they insert into patients.

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Critics of such arrangements say they give surgeons an incentive to do more operations, and that the conflict of interest has led to a spate of unnecessary back surgeries that waste health-care dollars and often do patients more harm than good. "Patients are having huge operations that are un-indicated because of this," says Scott Lederhaus, a neurosurgeon in Pomona, Calif., and member of the Association for Medical Ethics, an organization of doctors that focuses on conflicts of interest.

Dr. Lewis's lawyer says his client's financial interest in Spinal USA had nothing to do with his decision to operate on Mr. Moore. Dr. Lewis used Spinal USA implants because he helped design them and believed they "were the best on the market for the procedure," not because he stood to profit from them, says Mr. Johnson. He says Dr. Lewis "is truly sorry about Mr. Moore's death."

MORE

Read the itemized hospital bill for Mr. Moore's surgery.

View Document

VENIPUNCTURE LAB	1	16.62
COMP METABOLIC PANEL	1	220.51
CBC WITH DIFF	1	115.59
PT PROTHROMBIN TIME	1	61.98
PTT PARTIAL THROMBIN	1	98.27
IRIGLINS 4 OZ	1	22.10
GE NEUROLOGY REG ROOM	1	441.00
SUT VIC 2-0 SH J417H	1	11.70
SUT VIC 2-0 J726D	1	64.10
BONE WAX W310	1	21.70
SUT VIC 0 J840D	1	52.70
VITROS FOAM STRIP 1105	2	3,510.00
HW TRANS-1	1	6,590.00
SUT PDS II 1 D-8020	2	186.20
BONE GPT INFUSE 7510100	1	3,452.00
INST PROC GENESIS	4	788.00
SOLN NACL IRRIG 7138-36	1	11.70
CLIP APPLIER MCS/MSM	1	331.10
STAPLER SKIN	1	155.80
TOTAL BY MV 120 02 00000000	1	45.00

Read the warning letter the Food and Drug Administration sent to Spinal USA in 2007.

Medicare Records Reveal Troubling Trail of Surgeries (3/29/11)

Top Spine Surgeons Reap Royalties, Medicare Bounty (12/20/11)

Spinal-fusion surgery, which involves fusing together vertebrae, is used to treat a variety of back problems, particularly serious ones such as spinal fractures and scoliosis. It went from being the 37th most common hospital inpatient procedure in the U.S. in 1998 to the 16th most common in 2008, according to a study to be published soon in the journal *Spine*. It now accounts for around \$10 billion a year in U.S. medical spending.

Spine surgeons began implanting plates, rods and screws in patients' backs in the early 1990s. A federal antikickback law prohibits medical-device makers from paying surgeons to use their products. Mindful of the law, big device makers entered into partnerships with spinal surgeons, paying them consulting fees and royalties for help designing their products. In some cases, surgeons receiving payments would use that company's devices exclusively and would author research favorable to those products, company documents obtained by congressional investigators show.

Eventually, some entrepreneurial surgeons started making their own hardware. Surgeons often get to choose what devices they use, so some hospitals had no choice but to buy their products.

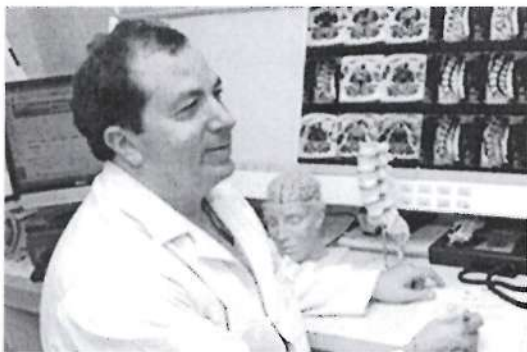
In addition to Dr. Lewis's Spinal USA, spinal-implant manufacturers created and co-owned by surgeons include Titan Spine in Mequon, Wis.; X-spine in Miamisburg, Ohio; and Innovasis in Salt Lake City. Surgeon Peter Ullrich, chief executive of Titan Spine, says he uses its products when he operates. X-spine and Innovasis didn't respond to requests for comment.

The Food and Drug Administration has a less stringent approval process for medical devices nearly identical to ones on the market. Surgeons only have to submit mechanical-testing data attesting that their implants are "substantially equivalent" to existing ones. The FDA usually gives its green light within 90 days.

Surgeon-owned implant makers, including Spinal USA, say they reduce health-care costs because their companies don't have marketing expenses and sales staffs, and they charge hospitals less than established medical-device makers do.

But the inherent conflict of interest is fueling concern. In June, five U.S. senators asked the Inspector General of the Department of Health and Human Services to open an investigation into physician-owned device companies, citing concerns that the surgeons involved have a financial incentive to "perform more procedures than are medically necessary."

A report provided to the agency by Utah Sen. Orrin Hatch, the senior Republican on the Senate Finance Committee, identified at least 20 states where surgeon-owned implant companies are present, and warned that they were spreading from spine surgery to other areas of medicine such as hip, knee and cardiac surgery.



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Neurosurgeon Adam Lewis at his Jackson, Miss. office. *THE CLARION-LEDGER*

Dr. Lewis, the Jackson, Miss., neurosurgeon, has long had financial ties to device makers. From 2004 to 2006, he received payments from Blackstone Medical Inc., according to his lawyer, Mr. Johnson.

A whistleblower lawsuit filed against Blackstone in a Massachusetts federal court by one of its former sales representative and a former distributor of its products alleges that the payments of up to \$8,000 a month were to induce Dr. Lewis and other surgeons to use the company's devices, in violation of the federal antikickback statute, rendering Medicare reimbursement claims fraudulent.

Mr. Johnson says the payments were legitimate consulting fees his client received for helping Blackstone develop two products. Blackstone has denied the allegations, and the case is pending.

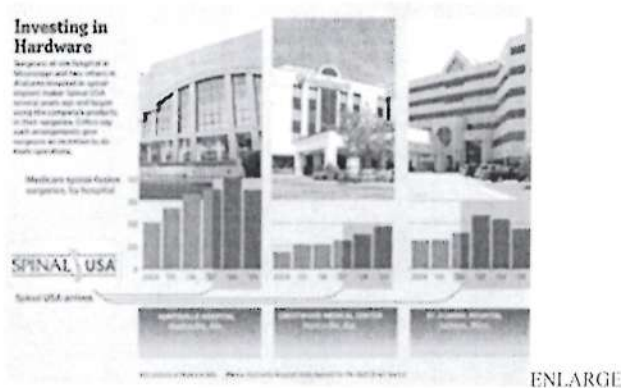
St. Dominic Hospital, where Dr. Lewis performs most of his surgeries, says it temporarily stopped doing business with Blackstone in September 2006 when the company declined to

provide it with information about its financial relationships with any hospital staff members. Blackstone has since been acquired by another company.

Dr. Lewis teamed up that same year with a former medical-device salesman and two other spine surgeons in Jackson and Hattiesburg, Miss. to manufacture their own devices. Their company, Spinal USA, is based in Pearl, Miss.

In the spring of 2007, FDA inspectors paid a surprise visit to Spinal USA's offices. They assessed the company with 14 violations, ranging from failing to maintain master records for its devices to having no system in place to track and label them, according to a warning letter the agency issued to the company. The violations were "symptomatic of serious problems," the warning letter stated.

A spokesman for Spinal USA says its rapid growth caused it to run afoul of FDA procedures. He says the company hired an experienced manager to oversee quality control in February 2008, and a second FDA inspection that September cleared the company of the violations. During a third visit in December 2010, FDA inspectors found problems with the way Spinal USA was storing bone products, which the company also addressed.



In the summer of 2007, Dr. Lewis and his partners recruited four spine surgeons in Huntsville, Ala. to invest in the company. Those surgeons, Gilbert Aust, Cyrus Ghavam, Morris Seymour and Larry Parker, switched to using Spinal USA implants in most of their surgeries, according to a local representative for a big medical-device maker.

Four more Huntsville spine surgeons subsequently joined Spinal USA, giving the company a relationship with eight of Huntsville's current 15 spine surgeons. Spinal USA also expanded to Mobile, Ala., where it recruited two surgeons.

Dr. Aust, who is chairman of Spinal USA, confirmed that he and Drs. Ghavam, Seymour and Parker are investors. The company declined to comment on its other surgeon investors.

At Huntsville Hospital, one of the city's two hospitals, 351 spinal-fusion surgeries were performed on Medicare patients in 2009, up from 333 in 2006, before Spinal USA came to town, a Wall Street Journal analysis of Medicare claims data shows. At Crestwood Medical Center, the city's other hospital, there were 187 such operations on Medicare patients in 2009, up from 107 in 2006, the analysis shows. Huntsville Hospital says it spent \$5.6 million on Spinal USA products in its most recent fiscal year.

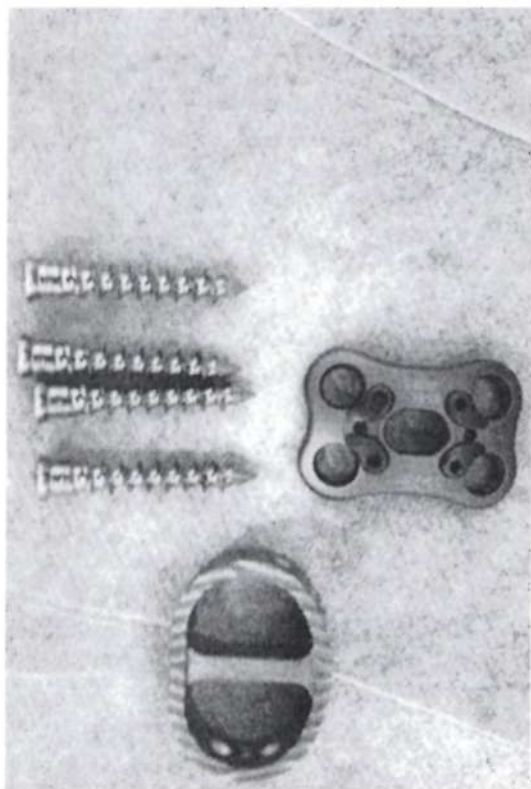
Dr. Aust attributes the surgery increases to more spine surgeons coming to town and to an aging local population.

Spinal USA's surgeon-owners sometimes operate on patients whose spines already contain implants made by other manufacturers, placed during prior surgeries. At times, as they insert additional Spinal USA devices, they remove some hardware made by the other manufacturers and replace it with Spinal USA products.

Dr. Aust says he performs such hardware replacements for medical reasons, not financial ones. He says he doesn't see anything wrong with the fact that they benefit him financially by contributing to Spinal USA's sales. "I know some people in the profession don't think it's ethical, but I just don't see it," he says.

The federal antikickback law doesn't specifically address the issue of surgeons using medical devices made by companies they co-own, but HHS's Office of the Inspector General has issued regulatory guidance for complying with the statute: Among other things, it advises that no more than 40% of a company be owned "by investors who are in a position" to "generate business" for it.

Dr. Aust says he and Spinal USA's other surgeon investors own "the majority of the company," but are working on lining up outside investors. The Spinal USA spokesman says its surgeon owners are in compliance with federal laws because their shares of profits are proportional to their ownership stakes, not to how much business they generate through their surgeries. He adds that more than 60% of the company's business is generated by surgeons who aren't owners.



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Spinal implants Dr. Lewis used on Mr. Moore. *THE WALL STREET JOURNAL*

Spinal USA declines to say how much its surgeon owners earn from the company. But a filing in the personal bankruptcy case of spine surgeon Michael Molleston, one of its investors, says Dr. Molleston received \$26,000 a month from Spinal USA as of Nov. 19, 2008, when the filing was made. Dr. Molleston couldn't be reached for comment.

The company says it generates more than \$20 million in annual revenues. Its spokesman notes, however, that its owners also are "personally responsible for debts of the company."

Medicare data show Dr. Lewis in Jackson performs spinal fusions more frequently than many of his peers. In 2008 and 2009, he performed 278 spinal fusions on Medicare patients, tenth most in

the nation, according to the Journal's analysis of Medicare claims data. In 150 of those cases, or 54%, the patients' diagnosis was degenerative disks.

On March 25, Mr. Moore went to see Dr. Lewis complaining of lower-back pain. After reviewing a magnetic resonance imaging of Mr. Moore's spine, taken a few weeks earlier, Dr. Lewis concluded that he suffered from a degenerative disk at the base of his spinal column, his medical records indicate.

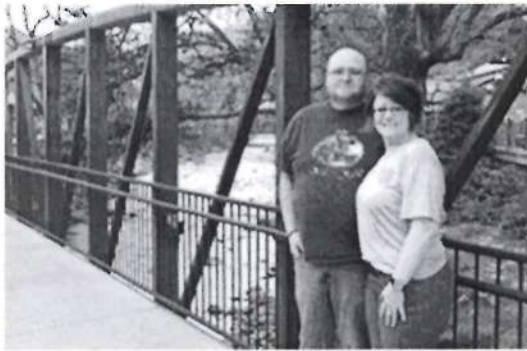
Mr. Johnson, Dr. Lewis's lawyer, says that, in addition to physical therapy, Mr. Moore already had tried chiropractic care, pain medication and steroid injections, to no avail, and his back pain was "significantly interfering with his lifestyle."

Dr. Lewis scheduled surgery—a 360-degree fusion. The procedure involves cutting open a patient's abdomen and back and fusing the vertebrae from front and rear, rather than from just one side.

Many people over age 55 show evidence of disk degeneration, even if they feel no pain, studies have shown. Advocates of treating back problems conservatively say pain associated with disk degeneration can be alleviated by physical therapy and rarely requires surgery. Other surgeons say fusion surgery can relieve pain from the condition.

Two spine surgeons who have reviewed Mr. Moore's medical records and films for the Journal say his disk's deterioration looked mild and did not require a 360-degree fusion. One of them, Charles Rosen, president of the Association for Medical Ethics and a spine surgeon at the University of California, Irvine School of Medicine, contends: "No operation of any kind could be justified." The other surgeon says a less aggressive procedure might have been warranted, although the patient's records don't suggest it was needed.

Both surgeons say Mr. Moore was a poor candidate for the 360-degree fusion because he had had 11 abdominal surgeries for an obstructed bowel. He also suffered from diabetes and had had a stent implanted to treat his heart disease.



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Gary Steve Moore and his wife, Kasey, in February 2011. Mr. Moore died April 7, hours after neurosurgeon Adam Lewis operated on his spine. *KASEY MOORE*

Mr. Johnson, Dr. Lewis's lawyer, says "different doctors can have different opinions about the best treatment option, but that doesn't make one right and one wrong." He says Mr. Moore wanted the surgery, and he had been cleared by other specialists who deemed him capable of withstanding the operation.

At St. Dominic Hospital, where the surgery was scheduled, a peer-review committee in 2010 had asked the hospital's chief of neurosurgery, John Lancon, to compile a report on 360-degree fusions of the lower spine following a series of complications involving the procedure, including two deaths, according to one person familiar with the matter. One of the patients who died had been operated on by Dr. Lewis, this person says. Dr. Lancon's report concluded that the risks of the surgery outweighed the benefits in most instances it was performed at the hospital, this person says.

Mr. Johnson says Dr. Lewis believes any deaths that followed 360-degree spinal fusions he performed "were from unrelated health issues" that developed after the surgeries. He declines to comment on any cases other than Mr. Moore's.

The peer-review committee decided to form a working group to review such cases before surgery, but under pressure from hospital management, shifted to reviewing the cases only after the surgeries were performed, the person familiar with the situation says. Consequently, Mr. Moore's surgery wasn't reviewed beforehand. St. Dominic's declined to comment on the matter, saying its peer-review process is confidential.

During the surgery on Mr. Moore, Dr. Lewis implanted a titanium Spinal USA cage and a Spinal USA plate with four screws. St. Dominic's charged the Moores \$13,960 for the implants. Spinal USA itself would have received no more than \$6,640 under the hospital's price-capping policy. Dr. Lewis received \$11,514 in surgical fees.

After the surgery, Mr. Moore was feverish and nauseous, says Kasey Moore, his widow. Soon he was gasping for air. Doctors and nurses tried to revive him for 40 minutes. He was pronounced dead at 5 p.m. In a discharge summary, Dr. Lewis wrote that Mr. Moore's heart gave out suddenly.

Neurosurgeons nationwide are sued for medical malpractice, on average, about once every two years. Dr. Lewis has been sued for malpractice 18 times since 2002. He has won two cases at trial, lost one, and 10 have been dismissed. Another five are pending, including one wrongful-death suit. (Mr. Moore's family has not sued.) His operating privileges at St. Dominic's have been suspended twice, court records show.

Mr. Johnson, his lawyer, says Dr. Lewis has never been in trouble with Mississippi's medical board, and most of the suits filed against him have proven to be without merit. Dr. Lewis is appealing the one case he lost at trial, in which a jury in May returned a \$553,000 verdict. Mr. Johnson says Dr. Lewis's suspensions occurred because he fell behind on patient charts.

Zoe Musick, Dr. Lewis's sister and his practice administrator, says his surgeries are always medically necessary and his financial interest in Spinal USA doesn't influence his decisions on whether or not to operate.

Dr. Lewis never told the Moores of his involvement in Spinal USA, according to Ms. Moore. A treatment authorization signed by Mr. Moore says patients might be referred to "a health care facility" with which their physician could have a "financial relationship." It says nothing about medical devices.

Ms. Moore says she would have liked to know that Dr. Lewis stood to profit from the implants he planned to insert in her husband's back. "It might have caused me to ask: Is the surgery really necessary, or is he out to make more money?" she says.

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